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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,201	01/30/2002	Mark Shannon	PB0178	2093

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07/01/2004

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EXAMINER	o
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ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,201

Applicant(s)

SHANNON, MARK

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-47 are pending in the application and are addressed herein.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, 8-12, 32, 33 and 39 drawn to a nucleic acid, vector, host cell, method of making a polypeptide, and diagnostic composition comprising the nucleic acid, classified in class 435, subclass 325.
 - II. Claim 7, drawn to a microarray, classified in class 435, subclass 283.1.
 - III. Claims 13-18, 34, 35 and 40, drawn to an isolated polypeptide, classified in class 530, subclass 350.
 - IV. Claims 19, 36-38 and 41, drawn to an antibody, classified in class 530, subclass 387.1.
 - V. Claim 20, drawn to a transgenic animal engineered to express a protein of interest, classified in class 800, subclass 8.
 - VI. Claim 21, drawn to a transgenic animal engineered to NOT express a particular protein (i.e., a knock-out), classified in class 800, subclass 8.
 - VII. Claim 22, drawn to a method for identifying an agent that modulates the expression of STTK, classified in class 435, subclass 4.
 - VIII. Claim 23, drawn to a method for identifying an agonist and antagonists of STTK, classified in class 435, subclass 4.
 - IX. Claim 24 and 42, drawn to a purified agonist, classified in class 530, subclass 300.

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- X. Claim 25 and 43, drawn to a purified antagonist, classified in class 530, subclass 300.
- XI. Claims 26-27, drawn to a method for identifying a specific binding partner, classified in class 424, subclass 9.1.
- XII. Claim 28, drawn to a purified binding partner, classified in class 530, subclass 350.
- XIII. Claim 29, drawn to a method for identifying a target nucleic acid in a sample, classified in class 435, subclass 6.
- XIV. Claim 30, drawn to a method for diagnosing a disease caused by a mutation in STTK, classified in class 424, subclass 9.1.
- XV. Claim 31, drawn to a method for diagnosing a disease caused by altered expression of STTK, classified in class 424, subclass 9.1.
- XVI. Claim 44, drawn to a method for treating a disease caused by decreased expression or activity of STTK using a nucleic acid, classified in class 514, subclass 44.
- XVII. Claim 44, drawn to a method for treating a disease caused by decreased expression or activity of STTK using a polypeptide, classified in class 514, subclass 2.
- XVIII. Claim 44, drawn to a method for treating a disease caused by decreased expression or activity of STTK using an agonist, classified in class 514, subclass 2.

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- XIX. Claim 45, drawn to a method for treating a disease caused by increased expression or activity of STTK using an antibody, classified in class 424, subclass 130.1.
- XX. Claim 45, drawn to a method for treating a disease caused by increased expression or activity of STTK using an antagonist, classified in class 514, subclass 2.
- XXI. Claim 46, drawn to a method for modulating the expression of a nucleic acid, classified in class 514, subclass 2.
- XXII. Claim 47, drawn to a method for modulating at least one activity of a polypeptide, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VI, IX, X and XII are products that are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated products because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

3. Inventions VII, VIII and XIII-XXII are unrelated processes. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated processes because they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

4. Inventions I and XVI, III and XVII, IX and XVIII, IV and XIX, as well as X and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant the process for using the product as claimed can be practiced with another materially different product and/or the product as claimed can be used in a materially different process of using that product. For instance, the nucleic acid of Group I can be used in a process of use that is materially different from that of Group XVI, such as producing a polypeptide or as a template for a PCR reaction. The polypeptide of Group III can be used in a process of use that is materially different from that of Group XVII, such as for producing antibodies specific for the polypeptide in an animal. The agonist of Group IX can be used in a process of use that is materially different from that of Group XVIII, such as for producing antibodies specific for the agonist. The antibody of Group IV can be used in a process of use that is materially different from that of Group XIX, such as in an immunoassay or for purifying the protein that the antibody specifically binds. The antagonist of Group X can be used in a process of use that is materially different from that of Group XX, such as for producing antibodies that are specific for the antagonist.

5. Inventions II, IV-VIII, XII-XV, XXI and XXII are unrelated products and processes. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions because they are not

disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for each Group is distinct (i.e. not co-extensive) to the searches required for the other Groups, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

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are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (571) 272-0756. The examiner can normally be reached on M-F (8:00-5:30) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
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DAVE T. NGUYEN
PRIMARY EXAMINER